

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/785,327 Confirmation No. : 9686
Applicant (s) : Sheskey TC/A.U. : 1615
Filed : Feb. 24, 2004 Examiner : C. Helm
Title : PROCESS FOR DISPERSING A FLUID IN A MASS
OF SOLID PARTICLES
Docket No. : 63633
Customer No. : 00109

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR §1.132

Dear Sir:

I hereby declare, acknowledging that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of this application or any patent issuing thereon, the following:

1. My name is Dr. Arthur H. Kibbe, and I am an expert in the field of pharmaceutical excipients, as evidenced in part by the fact that:
 - a) I am the Chair of Pharmaceutical Sciences for the Nesbitt School of Pharmacy, Wilkes University, in Wilkes-Barre, PA;
 - b) I was the editor-in-chief of the internationally recognized reference text, Handbook of Pharmaceutical Excipients, 3rd Edition; and
 - c) I also have served as the Director of Scientific Affairs of the American Pharmaceutical Association, and President of the American Pharmacists Association - Academy of Pharmacy Research and Science.
2. Other than the general academic concern that inventors be rewarded for innovation, I have no interest in the outcome of this case, to wit:
 - a) I am not an inventor on the above-referenced patent application;
 - b) I receive no research funding from The Dow Chemical Company or any affiliated company of the owner of the above-referenced application (Dow Global Technologies Inc.) (collectively, "Dow"); and
 - c) to the best of my knowledge, Wilkes University receives no significant funding from Dow.

Nor have I been offered any promises or incentives to submit this statement, rather, I volunteered when I heard that the above-referenced application was still in examination.

3. I have been informed that the Examiner of the above-referenced application is citing coating art against claims to a granulation process. While I am not a trained patent examiner, I can attest that those skilled in the art, such as myself, would not look to coating art to solve granulation problems. In layman's terms, granulation, or agglomeration, refers to adhering

numbers of particles together to make a granulate, usually to reduce dust, increase particle size uniformity, improve powder flow, or reduce segregation (for example, to ensure uniform drug dosage and improve tablet quality). Coating, on the other hand, refers to applying a layer of material to a substrate to isolate the substrate from an environment. In the art, great pains are taken to prevent coated particles from sticking together, i.e., much work in coating is precisely to avoid granulation.

4. As one skilled in the art, I believed before this invention that solving a granulation problem required some form of atomizing of the binding solution or solvent along with mixing to ensure even wetting of the powders and activation of the binder. This was followed by drying the wet mass either in a conventional oven or fluid bed dryer. No prior granulation process has used or even considered the application of a foam as a means of improving the uniformity of the granulation. This is why I consider foam granulation to be such an exciting breakthrough in the pharmaceutical field. The idea that a wet foam could be added to powder and achieve uniform distribution by simple mixing is unique and unexpected. One would expect some areas of the powder to have too much moisture and others not enough, and actives (if any) not to be evenly distributed. The fact that the above-referenced invention achieves uniform granulation (as described in the examples) is completely unexpected.

5. All statements made of my own knowledge are true, and all statements made on information and belief are believed to be true.

11/16/09
Date

Arthur H Kibbe
Arthur H Kibbe, Ph.D